Department of Veterans Affairs

Memorandum

Date: April 15, 2014

From: Associate Chief of Staff Research (151)

Subj: Addendum to R&D SOP 151-02 (version 3/12/2012): NOPP for Non-Veteran Subjects

To: Research Investigators
Thru: ACOS Research (151)

In collaboration with the Privacy Office the Research and Development Service has created this addendum to Research and Development Standard Operating Procedure 151-02 to clarify the Notice of Privacy Practices (NOPP) that is required to be provided to any non-Veteran subject enrolled in a clinical trial study.

A clinic trial study is a study that has randomization with clinical intervention (i.e. subject gets a drug product, direct clinical treatment, clinical procedure, etc). Studies whereby the subject completes a survey are not considered clinical trials.

The process to determination if NOPP is required is as follows:

1. At initial review or any time researchers request to include non-Veterans in a VA clinical trial the IRB will make an assessment to determine if the NOPP needed.

2. If PI has received written IRB approval to include non-Veteran subjects in the clinical trial, the PI will provide a copy of the NOPP to the non-Veteran subject and have the subject sign the NOPP acknowledgement form (VA Form 10-0483) at the first visit.

3. The PI will send a copy of the form to HIMS for scanning into CPRS and keep the original in the subject's research file. NOTE: If the form is not received by the non-Veteran subject, an administrative note (can be entered by the Clinical Coordinator) must be entered in CPRS indicating the good faith efforts made to get the form signed and the reason the form could not be signed.

Please contact the HRPP Office if you have any questions.

Thank you,

DOUGLAS S. WALSH, MD, MS
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Dermatology and R&D Services

To Be Used In Lieu Of VA FORM 2105

References:
VHA Handbook 1605
Department of Veterans Affairs VHA NOPP (September 23, 2013)
VA Form 10-0483